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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/139,058	08/24/98	WOODLE	M 5325-0122.20

DEHLINGER & ASSOCIATES
PO BOX 60850
PALO ALTO CA 94306

HM42/1211

EXAMINER	
KISHORE,G	
ART UNIT	**PAPER NUMBER**
1615	3

DATE MAILED: 12/11/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 8-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 8-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

* U.S. GPO: 1996-410-238/40050

DETAILED ACTION

Claims included in the prosecution are 9-20; these claims however, have been renumbered as claims 8-19 in accordance with rule 126, since there is no claim 8 in the application.

Claim Rejections - 35 U.S.C. § 112

1. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

2. **Claims 8 and 11-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific polymers recited in claim 10, does not reasonably provide enablement for generic 'hydrophilic biocompatible polymer'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term, 'hydrophilic polymer' is a generic term which encompasses polymers such as proteins, carbohydrates and nucleic acids, just to name a few; instant specification has no support for the generic expression. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to specific polymers disclosed as having the intended function.**

3. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

4. **Claims 8-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

'Several fold' in the independent claims is deemed to be indefinite since it is not a positive expression in terms of numbers.

The method claim 14 is deemed to be indefinite since it fails to recite the method of preparation steps.

Double Patenting

5. **The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).**

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. **Claims 8-12, 14-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,013,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic hydrophilic polymer encompasses PEG in the claims of said patent.**

7. **Claims 8-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,213,804. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic 'hydrophilic polymer' encompasses the specific polymers in the claims of said patent.**

8. **Claims 8-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-13 and 17-18 of copending Application No. 09/139,158. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic 'hydrophilic polymer' encompasses the specific polymers in the claims of said copending application.**

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 8-19 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 5,843,473 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: instant claims are drawn to compositions and the method of preparation of the compositions; patented claims are drawn to a method of treatment using the same claimed composition which is fully disclosed in the specification of said patent.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

This rejection will be reconsidered once the determination is made whether instant claims were restricted in the parent case.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 8-9 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sears (EP 0 118 316).

Sears discloses synthetic lipids formed by reacting phosphatidylethanolamine and polyethylene glycol. This amphiphilic compound is used to encapsulate drugs.The method of encapsulation involves the evaporation to dryness of said synthetic lipid and hydrating it with an aqueous medium and vortexed (note the abstract, columns 2-5, Examples 10-14). Instant 'therapeutic compound avtive against the pathogen causing the infection' is deemed be included in 'drug' taught by Sears.

> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

12. Claims 8-9 and 11-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Popescu (4,981,692).

Popescu discloses liposome formulations which contain an amphipathic lipid and cholesterol-PEG and gentamycin for the treatment of Brusella infections (note the abstract, col. 3, line 63 through col. 4, line 8, col. 6, lines 13-19, Examples and claims).

Claim Rejections - 35 U.S.C. § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was**

made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sears (EP 0 118 316).

Sears discloses synthetic lipids formed by reacting phosphatidylethanolamine and polyethylene glycol. This amphiphilic compound is used to encapsulate drugs. The method of encapsulation involves the evaporation to dryness of said synthetic lipid and hydrating it with an aqueous medium and vortexed (note the abstract, columns 2-5, Examples 10-14). Although Sears does not teach instant drugs and instant polymers, it is deemed to be within the skill of the art to encapsulate any drug or use similar hydrophilic polymers with the expectation of obtaining similar results.

15. Claims 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff ((4,897,384) or Popescu (4,981,692) in view of Yoshioka (5,593,622).

Janoff teaches gentamycin containing liposomes (note the abstract, examples and claims). Janoff however, does not teach that the phospholipids used in the formation of liposomes be attached with the hydrophilic polymer such as polyethylene glycol (PEG).

As pointed out above, Popescu teaches liposome formulations containing gentamycin. Popescu although teaches that cholesterol-PEG could be used in the liposomes, does not teach that phospholipids used in the formation of liposomes be attached with the hydrophilic polymer, polyethylene glycol (PEG).

Yoshioka teaches that when phospholipids which are attached to PEG are used in the formation of liposomes, the hydrophilic moiety of PEG prevents the adsorption of plasma proteins on the liposomes and the subsequent agglutination of liposomes (note the abstract). In essence Yoshioka indirectly teaches that the stability of the liposomes is increased.

The atttachment of PEG to the surface of the liposomes (by coupling with the phospholipid) taught by Janoff or Popescu would have been obvious to one of ordinary skill in the art because PEG prevents the adsorbtion of plasma proteins on the liposomes and the subsequent agglutination of liposomes as taught by Yoshioka.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

December 8, 1998